

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE Symmetry Mojdeh Bahar Symmetry Mojdeh Bahar

re Patent Application of: Harry R. Davis et al.

Serial No.:

10/057.629

Filed: January 25, 2002

For:

Use of Substituted Azetidinone

Compounds for the Treatment

Of Sitosterolemia

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Group Art Unit: 1617

Atty. Docket No.: CV01382K

## RESPONSE TO RESTRICTION REQUIREMENT AND ELECTION OF SPECIES

This is in response to the Office Action mailed on July 2, 2003, in the aboveidentified patent application.

Claims 1-58 are pending in the application. A two-way restriction requirement was set forth at page 2 of the Office Action and an election of species requirement was set forth at pages 2-3 of the Office Action. For brevity, these rejections are not repeated herein but reference is made to the Office Action. Applicants respectfully traverse and request reconsideration and withdrawal of the restriction and election of species requirements.

Applicants believe that when there is a linking claim encompassing the scope of pharmaceutical compositions comprising compounds and methods of treatment using the compositions, it is inappropriate to restrict the invention. Applicants believe that due to such commonality a complete examination of claims 1-58 would not cause undue burden. Therefore, reconsideration and withdrawal of the restriction requirement is respectfully requested.

> I hereby certify that this correspondence is being deposited with the U.S. Postal Service First Class Mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on August 1, 2003.

Ann Cannoni

Registration No. 35,972



## PROVISIONAL RESPONSE TO RESTRICTION REQUIREMENT AND ELECTION OF SPECIES

To facilitate prosecution of the application and in order to comply with the Examiner's requirements, Applicants hereby provisionally elect with traverse the claims of Group 1 (claims 1-24, 32-45 and 48-56) for initial examination in this application.

Applicants provisionally elect with traverse cholestyramine as the lipid-lowering agent for initial examination. Cholestyramine is a bile acid sequestrant and is disclosed at page 41, line 22 and elsewhere throughout the application. The claims readable thereon include claims 15 and 19-21, 28, 32, 43-47, and 57-58.

Applicants provisionally elect with traverse the compound of Formula (VIII) (ezetimibe) (shown at page 32 of the specification) for initial examination in this application. The claims readable thereon include claims 1, 8-9, and 13-58.

Applicants provisionally elect with traverse simvastatin as the third therapeutic agent for initial examination in this application. Simvastatin is disclosed at page 42, line 17 and elsewhere throughout the application. The claims readable thereon are claims 15-24, 28-31, 33, 41, 42 and 57.

Examination on the merits for claims 1-58 is respectfully requested.

Respectfully submitted,

ANN MARIE CANNONI Registration No. 35,972 Attorney for Applicant

Date: August 1, 2003

SCHERING CORPORATION

Patent Department, K-6-1-1990

2000 Galloping Hill Rd.

Kenilworth, NJ 07033-0530

Telephone: (908) 298-5024 Facsimile No.: (908) 298-5388 Attorney Docket No.: CV

Application No.: 10/057,629

Filing Date: 01/25/2002

Inventor: Harry R. Davis et al.

Under the Paperwork Reduction Act of 1999

Approved for use

U. S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE are required to respond to a collection of information unless it contains a valid OMB control number

## Certificate of Mailing under 37 CFR 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

### **Commissioner for Patents**

P.O. Box 1450

Alexandria, VA 22313-1450

08/01/2003

Date

Signature

Ann Marie Cannoni, Reg. No. 35,972

Typed or printed name of person of signing Certificate

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Documents submitted:

Response to Restriction Requirement and Election Species - 2 Pages

Response Transmittal Form PTO/SB/21 - 1 Page

Certificate of Mailing - 1 Page

Post Card

Burden Hour Statement: This form is estimated to take 0.03 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231, DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS, SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

E vc, ()			PTO/SB/21 (03-03 Approved for use through 04/30/2003. OMB 0651-003
		U.S. Pate	nt and Trademark Office; U.S. DEPARTMENT OF COMMERCE on of information unless it displays a valid OMB control number
Under the Paperwork Reduction Act of	1995, no persor	Application Number	
TRANSMITTAL FORM  (to be used for all correspondence after initial filing)		Filing Date	10/057,629
		First Named Inventor	01/25/2002
			Harry R. Davis, et al.
		Art Unit	1617 EC 2
		Examiner Name	Mojdeh Bahar
Total Number of Pages in This Submission	1 4	Attorney Docket Number	CV01382K
	ENC	LOSURES (Check all tha	at apply)
Fee Transmittal Form  Fee Attached  Amendment/Reply  After Final  Affidavits/declaration(s)  Extension of Time Request  Express Abandonment Reques  Information Disclosure Stateme  Certified Copy of Priority Document(s)  Response to Missing Parts/ Incomplete Application  Response to Missing Parts/ under 37 CFR 1.52 or 1	nt Rema	Drawing(s)  Licensing-related Papers  Petition  Petition to Convert to a  Provisional Application  Power of Attomey, Revocation  Change of Correspondence Add  Terminal Disclaimer  Request for Refund  CD, Number of CD(s)	After Allowance Communication to Group  Appeal Communication to Board of Appeals and Interferences  Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)  Proprietary Information  Status Letter  Other Enclosure(s) (please Identify below):  Certificate of Mailing - 1 Page  Post Card
<del>_</del> <del>_</del>	NATURE	OF APPLICANT, ATTORN	IEY, OR AGENT
Firm or Individual Ann Marie Cannor Signature	i, Reg. No.	35,972	
Date August 1, 2003			
	CERTIFIC	CATE OF TRANSMISSIO	N/MAILING
I hereby certify that this correspondence is be first class mail in an envelope addressed to:			with the United <u>States Postal Service with sufficient</u> postage as this date:
Typed or printed			
Signature			Date

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.